

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

PLUMBERS AND PIPEFITTERS LOCAL)	
572 PENSION FUND, on behalf of itself and)	
all others similarly situated,)	
) Case No.:	
Plaintiff,)	
) <u>CLASS ACTION</u>	
v.)	
ASTRAZENECA PHARMACEUTICALS LP,)	
a Delaware Corporation, ASTRAZENECA LP,)	
ASTRAZENECA AB, AKTIEBOLAGET)	
HASSLE)	
) <u>COMPLAINT FOR DAMAGES</u>) <u>AND INJUNCTIVE RELIEF</u>	
Defendant.)	
) <u>JURY TRIAL DEMANDED</u>	

Plaintiff Plumbers and Pipefitters Local 572 Pension Fund ("Local 572"), by its attorneys, upon personal knowledge as to facts pertaining to itself, and upon information and belief as to all other matters, alleges the following:

NATURE OF ACTION

1. This is a nationwide class action seeking damages and other equitable relief arising from Defendant's anti-competitive conduct in connection with the manufacture and marketing of the brand-name drug Toprol-XL®, a drug used to remedy, among other things, hypertension. Defendant's unlawful conduct prevented generic versions of Toprol-XL® from entering the United States market, thereby causing injury to Plaintiff and members of the Class. The generic name for Toprol-XL® is metoprolol succinate.

2. Metoprolol succinate is a compound used to treat angina, hypertension and congestive heart failure. Originally invented in Sweden, metoprolol succinate is offered in several extended release dosages. AstraZeneca holds two patents claiming metoprolol succinate and its "sustained release" formulation. These patents are United States Patent 5,001,161 (the

‘161 patent) and United States Patent 5,081,154 (the ‘154 patent). There are currently no generic competitors to AstraZeneca’s brand name Toprol-XL® version of metoprolol succinate on the market. During 2005 alone, Toprol-XL® provided AstraZeneca with yearly sales in excess of \$1.29 billion.

3. In response to a series of Abbreviated New Drug Applications (“ANDAs”) filed by potential generic competitors KV Pharmaceutical Co. (“KV Pharmaceutical”), Andrx Pharmaceuticals, LLC and Andrx Corp. (“Andrx”) and Eon Labs, Inc. (“Eon”), AstraZeneca commenced a string of baseless patent infringement actions in an attempt to prevent generic versions of Toprol-XL® from entering the United States market.

4. AstraZeneca’s patent infringement complaints against KV Pharmaceutical, Andrx and Eon were consolidated by August 11, 2004 order of the Judicial Panel on Multidistrict Litigation and transferred to the U.S. District Court for the Eastern District of Missouri. Ultimately, the Court concluded that the generic products did not infringe upon AstraZeneca’s patents because AstraZeneca’s patents were themselves invalid as “obvious” double patenting, as well as unenforceable for equitable reasons.

5. AstraZeneca’s prosecution of baseless patent litigation against the filers of ANDA applications was part of a concerted effort to monopolize the United States market for extended release metoprolol succinate and thwarted the entry of generic versions of Toprol-XL® into the United States market.

6. As a direct and proximate result of Defendant’s unlawful conduct, consumers have been denied the benefits of free and unrestrained competition in the extended release metoprolol succinate market. More specifically, Plaintiff has been denied the opportunity to offer its beneficiaries the choice between the brand name prescription drug and lower priced

generic versions, and Plaintiff and the Class have been forced to pay more for the brand version of the drug.

JURISDICTION AND VENUE

7. This action is brought pursuant to various state antitrust laws for damages stemming from Defendant's illegal monopolistic conduct. Plaintiff is a citizen of a different state than Defendant and the amount in controversy clearly exceeds \$5,000,000. Therefore, the Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d).

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(a) because Defendant resides in this district and a substantial part of the events giving rise to this claim occurred here. Plaintiff has participants and beneficiaries in this District who have purchased Toprol-XL® and who have been reimbursed for those purchases by Plaintiff.

PARTIES

9. Plaintiff Local 572 is a trust fund administered pursuant to the requirements of the Taft-Hartley Act, 29 U.S.C. §186, by an equal number of trustees appointed by labor representatives and union representatives. Local 572 is an "employee welfare benefit plan" and "employee benefit plan" maintained pursuant to §302(c)(5) of the Labor Management Relations Act ("LMRA"), 29 U.S.C. § 186(c)(5), and as defined by § 1002(1) and (3) of the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, *et seq.* As such, Local 572 is a legal entity entitled to bring suit in its own name pursuant to 29 U.S.C. § 1132(d). Local 572's office is located in Davidson County, Tennessee.

10. Local 572's health and medical benefits are provided under a written benefit plan. Each plan contains certain provisions under which Local 572 is subrogated to and assigned all the rights and causes of action of its participants and beneficiaries for whom it pays benefits. Many of Local 572's participants and beneficiaries were purchasers of Toprol-XL® during the

class period described below. Local 572 has paid for or reimbursed its participants' and beneficiaries' purchases of Toprol-XL® during the relevant period.

11. Defendant AstraZeneca Pharmaceuticals, LP is a company organized and existing under the laws of Delaware, which distributes, markets, sells, and/or profits from pharmaceutical products including Troprol-XL® throughout the United States. Its U.S. Corporate headquarters is located at 1800 Concord Pike, Wilmington, Delaware.

12. Defendant AstraZeneca, LP is a Delaware corporation with its principal place of business in Wilmington, Delaware.

13. Defendant AstraZeneca AB is a company organized and existing under the laws of Sweden, having its principal place of business at S151 85, Sodertalje, Sweden.

14. Defendant Aktiebolaget Hassle is a company organized and existing under the laws of Sweden, having its principal place of business at Molndal, Sweden. Aktiebolaget Hassle is a wholly owned subsidiary of AstraZeneca AB.

15. Various persons, partnerships, sole proprietors, firms, corporations and individuals not named as defendants in this lawsuit, and individuals, the identities of which are presently unknown, may have participated as co-conspirators with defendants in the offenses alleged in this Complaint, and have performed acts and made statements in furtherance of the alleged conspiracy to monopolize.

RELEVANT MARKET

16. During the class period, (May 6, 2003 to the present), the relevant product market is all metoprolol succinate extended release products – *i.e.*, Toprol-XL® (in all its forms and dosage strengths) and bioequivalent metoprolol succinate products sold in the United States.

17. During the class period, Defendant's share of the relevant market was 100% and Defendant maintained monopoly power in the relevant market during that time period.

MARKET EFFECTS

18. The acts and practices of Defendant, as herein alleged, had the purpose and effect of unreasonably injuring competition by protecting Toprol-XL® from generic competition in the relevant market.

19. If a generic competitor had been able to enter the relevant market and compete with Defendant, End-Payors such as Plaintiff would have been free to substitute a lower-priced generic for the higher-priced brand name drug and the Class would have paid less for all metoprolol succinate extended release products, including Toprol-XL®. Pharmacists generally are permitted, and in some instances required, to substitute generic drugs for their branded counterparts, unless the prescribing physician has directed that the branded product be dispensed. In addition, there is a ready market for generic products because certain third-party payors of prescription drugs (*e.g.*, managed care plans) encourage or insist on the use of generic drugs whenever possible. A generic product can quickly and efficiently enter the marketplace at substantial discounts, generally leading to a significant erosion of the branded drug's sales within the first year.

20. By preventing generic competitors from entering the market, Defendant injured Plaintiff and the other Class members in their business or property by causing them to pay more for Toprol-XL® than they otherwise would have paid. Defendant's unlawful conduct deprived Plaintiff and other End-Payors of the benefits of competition that the antitrust laws and consumer protection laws are designed to preserve.

FACTUAL ALLEGATIONS

A. Federal Regulation of Prescription Drugs

1. Brand-name Drugs v. Generic Drugs

21. The laws governing pharmaceutical products are meant to balance the competing policy goals of providing new drug inventors an economic return on their investment while also ensuring consumers access to additional and more affordable generic versions of brand name drugs.

22. The manufacture, marketing, distribution and sale of prescription drugs is one of the most profitable industries in the United States. The U.S. market accounts for more than 40% of the world's prescription pharmaceutical revenues. The cost of prescription drugs in the United States has been rising at double digit rates for years, and the cost of drugs dispensed in the United States in the most recent year exceeded \$153 billion.

23. The availability of generic drugs has been one of the most effective means of lowering the cost of prescription drugs. Generic drugs, which also must be approved by the FDA, have the same active chemical composition and provide the same therapeutic effects as the pioneer brand-name drugs upon which they are modeled. The FDA will assign an "AB" rating to generic drugs that are bioequivalent to pioneer or brand-name drugs.

24. To be deemed a therapeutic equivalent and assigned an "AB" rating by the FDA, the generic drug must contain the same active ingredient(s); dosage form and route of administration; and strength. If so, the generic drug, as a therapeutic equivalent, can be substituted (and in some instances must be substituted) for the pioneer or brand-name drug at the pharmacy dispensing the drug.

25. Generic drugs are generally priced substantially below the brand-name drugs to which they are bioequivalent. A 1998 study conducted by the Congressional Budget Office in

August 2000 observed, “[b]ecause generic drugs are not patented and can be copied by different manufacturers, they often face intense competition, which usually results in much lower prices than brand-name drugs.”

26. The Federal Trade Commission (“FTC”) estimates that the first generic manufacturer to enter the market typically charges between 70% and 80% of the price of the brand-name drug. As additional manufacturers bring generic versions of the drug to market, the price continues to drop.

27. A brand-name drug loses a significant portion of its market share to generic competitors soon after the introduction of generic competition, even if the brand-name manufacturer lowers prices to meet competition. The 1998 CBO study estimates that generic drugs capture at least 44% of the brand-name drug’s market share in just the first year of sale.

2. Prescriptions for Generic Drugs

28. Generic drugs are drugs that the FDA has found to have the same active chemical composition and provide the same therapeutic effects as the pioneer or brand-name drug.

29. If a generic version of a brand-name drug exists and the physician has not specially indicated on the prescription “DAW” or “dispense as written” (or similar indication, the wording of which varies slightly from state to state), then: (a) for consumers covered by most insurance plans, the pharmacist will substitute the generic drug; and (b) for consumers whose purchases are not covered by insurance plans, the pharmacist will offer the consumer the choice of purchasing the branded drug, or the AB-rated generic at a lower price.

30. Once a physician writes a prescription for a brand-name drug such as Toprol-XL®, that prescription defines and limits the market to the drug’s name or its AB-rated generic equivalent. Only drugs which carry the FDA’s AB generic rating may be substituted by a pharmacist for a physician’s prescription for a brand-name drug.

3. **New Drug Applications (NDA)**

31. The statute regulating the manufacture and distribution of drugs and medical devices in the United States is the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (The “FD&C Act”).

32. Under the FD&C Act, approval by the FDA, the governmental body charged with regulation of the pharmaceutical industry, is required before a company may begin selling a new drug in interstate commerce in the United States. 21 U.S.C. § 355(a). Premarket approval for a new drug must be sought by filing a new drug application (“NDA”) with the FDA under § 355(b) of the FD&C Act demonstrating that the drug is safe and effective for its intended use.

33. New drugs that are approved for sale in the United States by the FDA are typically covered by patents, which provide the patent owner with the right to exclude others from making, using or selling that new drug in the United States for the duration of the patents, plus any extension of the original patent period granted pursuant to the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355 (“Hatch-Waxman Act”).

34. Pursuant to 21 U.S.C. § 355(b), in its NDA the pioneer drug manufacturer must list all patents that claim the drug for which FDA approval is being sought, or that claim a method of using the drug, and with respect to which a claim of patent infringement could reasonably be asserted against an unlicensed manufacturer or seller of the drug.

35. Once the NDA is approved, any claimed patents are listed with the NDA in a publication known as the Approved Drug Products With Therapeutic Equivalence Evaluations. The publication is commonly called the “Orange Book.”

36. Pursuant to 21 U.S.C. § 355(c)(2), if, after its NDA is approved, the pioneer drug manufacturer is issued a new patent that claims the drug or methods of its use, the company must supplement its NDA by listing such new patent within 30 days of issuance, whereupon the FDA

publishes the new patent in a supplement to the Orange Book. The FDA is required to accept as true patent information it obtains from patent holders, such as whether a patent covers a particular drug product. If an unscrupulous patent holder is willing to provide false information to the FDA to delay the onset of generic competition, the FDA is powerless to stop it.

37. Once the safety and effectiveness of a new drug is approved by the FDA, it may be used in the United States only under the direction and care of a doctor who writes a prescription specifying the drug, which must be purchased from a licensed pharmacist. Generally, the pharmacist must, in turn, fill the prescription with the drug specified by the physician unless a generic version is available that has been approved by the FDA for substitution as a bioequivalent.

a. **Abbreviated New Drug Application (“ANDAs”) For Generic Drugs**

38. Congress enacted the Hatch-Waxman Act in 1984 to establish an abbreviated process to expedite and facilitate the development and approval of generic drugs. Consumers benefit from the choice and competition. To effectuate its purpose, the Hatch-Waxman Act permits a generic drug manufacturer to file an Abbreviated New Drug Application (“ANDA”), which incorporates by reference the safety and effectiveness data developed and previously submitted by the manufacturer of the original, pioneer drug.

39. The Hatch-Waxman Act permits ANDA applicants to perform all necessary testing, submit an application for approval, and receive tentative approval before the relevant patents expire. Prior to the Hatch-Waxman Act, a generic applicant had to wait until all patents had expired to begin the approval process or otherwise face an infringement suit.

40. The ANDA must include information concerning the applicant's position *vis-à-vis* the patent that the pioneer drug manufacturer claims applies to the drug. Therefore, the ANDA filer must make one of four certifications:

- i. that no patent for the pioneer drug has been filed with the FDA (a "Paragraph I Certification");
- ii. that the patent for the pioneer drug has expired (a "Paragraph II Certification");
- iii. that the patent for the pioneer drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or
- iv. that the patent for the pioneer drug is invalid or will not be infringed by the proposed generic company's product (a "Paragraph IV Certification").

21 U.S.C. § 355(j)(2)(A)(vii). In the case of a patent that has not yet expired, the ANDA applicant's only certification options are Paragraph III or IV Certifications.

41. The brand-name drug patent owner, upon receiving a Paragraph IV Certification from an ANDA applicant, has 45 days to initiate a patent infringement suit against the applicant. See 21 U.S.C. § (j)(5)(5)(iii). If a patent infringement suit is brought within the 45-day window, FDA approval of the ANDA is automatically postponed until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement.

42. Accordingly, brand-name drug patent holders need only file a patent infringement lawsuit within 45 days of receipt of Paragraph IV Certification in order to automatically block an ANDA applicant's generic drug from entering the market for up to 30 months.

B. AstraZeneca's Unlawful Monopolistic Practices

1. AstraZeneca Knew Its '154 and '161 Patents Were Invalid

43. Metoprolol succinate is a drug used to treat angina, hypertension and congestive heart failure. It was originally developed in the 1970s. The first patent application claiming a sustained release formulation of metoprolol succinate was filed in September 1986, and issued as United States Patent No. 4,957,745 (the '745 patent). A patent claiming a second formulation of sustained release metoprolol succinate based upon a double-coated tablet issued on October 25, 1988 as United States Patent No. 4,780, 318 (the '318 patent).

44. On March 19, 1991, Patent No. 5,001,161 (the '161 patent), entitled "Pharmaceutical Composition Comprising Metoprolol Succinate," was issued to Aktiebolaget Hassle, Molndal, Sweden, upon assignment from the inventors Curt H. Appelgren ("Appelgren") and E. Christina Eskilson ("Eskilson"). The '161 patent claims pharmaceutical compositions comprising metoprolol succinate and a sustained release carrier. AstraZeneca is the current owner of the '161 patent since 1991.

45. On January 14, 1992, Patent No. 5,081,154 (the '154 patent), entitled "Metoprolol Succinate," was issued to Aktiebolaget Hassle, Molndal, Sweden, upon assignment from the inventors Appelgren and Eskilson. The '154 patent claims the compound metoprolol succinate. AstraZeneca is the current owner of the '154 patent since 1992.

46. In connection with its filings for the '161 and '154 patents with the United States Patent and Trademark Office ("USPTO"), AstraZeneca failed to disclose a material dispute with a competitor regarding the inventorship of metoprolol succinate. Between 1985 and 1988, AstraZeneca and Lejus Medical contested the issue of who invented metoprolol succinate. Although AstraZeneca claimed that Appelgren and Eskilson invented the compound in the 1980s, Lejus contended that a chemist employed by AstraZeneca named Toivo Nitenberg first

synthesized the drug in 1971. Because AstraZeneca's claims for patents '161 and '154 would be invalid due to this prior art, Defendant intentionally chose not to disclose this dispute to the USPTO. This information would have been material – and AstraZeneca knew it would have been material – to the USPTO in deciding whether to issue Defendant's '154 and '161 patents and, as such, its nondisclosure constituted fraud on the PTO.

47. In addition, AstraZeneca knew that its '161 and '154 patents were invalid for double patenting, because they encompass the claims of the '318 and '745 patents. The '318 patent is a delivery formulation for a specific type of extended release metoprolol succinate. Claim 6 of the patent is oral controlled release pharmaceutical compositions with a core of the active drug, surrounded by a coating diffusion membrane and a second coating that resists dissolution in the pH of the stomach. Claim 8 of the '318 patent specifies a particular formulation of the drug to allow for controlled release in or near the colon.

48. Like the '318 and '745 patents, the '161 patent states that "[t]he object of the present invention is to obtain a therapeutically active compound intended to be released close to or within the colon, and particularly to such active compounds which are soluble in the pH range 1 to 8." Because the '161 patent claims the same invention as the prior patents, it is invalid.

49. AstraZeneca also knew that the '154 patent was invalid. The '154 patent claims only the compound metoprolol succinate itself. Accordingly, the '154 patent is a genus of the species claimed by the earlier-issued '318 patent, and is void for double patenting. Similarly, the '154 patent is rendered invalid for double patenting of the claims contained in the earlier-filed '161 patent.

2. AstraZeneca Prosecutes Meritless Sham Litigation

50. Despite the invalidity of the underlying patents, AstraZeneca filed baseless lawsuits against each manufacturer who sought to enter the market with a generic formulation of Toprol-XL®.

KV Pharmaceutical Litigation

51. By a Notice to AstraZeneca pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) dated early 2003, KV Pharmaceutical stated that it had submitted an ANDA to the FDA, seeking approval to manufacture, use and sell metoprolol succinate extended release tablets as a generic version of Toprol-XL® products. In the Notice, KV Pharmaceutical notified AstraZeneca that as part of its ANDA it had filed a Paragraph IV Certification with respect to the '161 and '154 patents.

52. In response, AstraZeneca filed a complaint for patent infringement against KV Pharmaceutical on May 6, 2003. After receiving additional written notices that Andrx had submitted ANDAs and accompanying certifications, AstraZeneca filed additional complaints against KV Pharmaceutical raising similar claims regarding KV Pharmaceutical's attempts to bring to market the drug in other dosages, on August 22, 2003, September 16, 2004, and October 21, 2005.

53. As of the date of this Complaint, KV Pharmaceutical's ANDAs have not yet been approved by the FDA. However, had KV Pharmaceutical not had to defend the baseless patent infringement lawsuits brought by Defendant against it, KV Pharmaceutical could have and would have expended its resources obtaining approval for its ANDA and bringing its versions of generic metoprolol succinate to market.

Andrx Litigation

54. By a Notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) to AstraZeneca dated December 24, 2003, Andrx stated that it had submitted an ANDA to the FDA, seeking approval

to manufacture, use and sell metoprolol succinate extended release tablets in a generic version of Toprol-XL® products. In the Notice, Andrx notified AstraZeneca that as part of its ANDA it had filed a Paragraph IV Certification with respect to the '161 and '154 patents.

55. In response, AstraZeneca filed a complaint for patent infringement against Andrx on February 5, 2004. After receiving additional written notices that Andrx had submitted ANDAs and accompanying certifications relating to 50 mg, 25 mg and 100/200 mg dosages of Toprol-XL® products, AstraZeneca filed additional lawsuits against Andrx on September 7, 2004, October 6, 2004 and February 15, 2005, respectively.

56. As of the date of this Complaint, Andrx's ANDAs have not yet been approved by the FDA. However, had Andrx not had to defend the baseless patent infringement lawsuits brought by Defendant against it, Andrx could have and would have expended its resources obtaining approval for its ANDA and bringing its versions of generic metoprolol succinate to market.

Eon Litigation

57. By a Notice to AstraZeneca dated February 21, 2004, Eon stated that it had submitted an ANDA to the FDA, seeking approval to manufacture, use and sell metoprolol succinate extended release tablets as generic versions of Toprol-XL® products. In the Notice, Eon notified AstraZeneca that as part of its ANDA it had filed a Paragraph IV Certification with respect to the '161 and '154 patents.

58. In response, AstraZeneca filed a complaint in the U.S. District Court for the District of Delaware, alleging patent infringement against Eon on April 5, 2004. AstraZeneca filed an additional lawsuit against Eon in the U.S. District Court for the Eastern District of Missouri on September 2, 2004 containing similar allegations.

59. As of the date of this Complaint, Eon's ANDA has not yet been approved by the FDA. However, had Eon not had to defend the baseless patent infringement lawsuit brought by Defendant against it, Eon could have and would have expended its resources obtaining approval for its ANDA and bringing its version of generic metoprolol succinate to market.

60. On January 18, 2005, the United States District Court for the Eastern District of Missouri granted summary judgment to Andrx, Eon and KV Pharmaceutical, holding that AstraZeneca's '161 and '154 patents were invalid for double patenting. In so holding, the court stated that "I find by clear and convincing evidence that Astra's '161 patent and '154 patent are invalid on the basis of double patenting over the '318 patent. I also find by clear and convincing evidence that the '161 patent is not entitled to priority to the '318 patent application filing date. As a consequence I find that the '161 patent is invalid as anticipated."

61. Further, the Court found that Defendant's '161 and '154 patents were unenforceable based on Astra's inequitable conduct in the prosecution of these patents in the United States Patent and Trademark Office. AstraZeneca failed to disclose to the USPTO the material dispute it had with Lejus concerning inventorship of metoprolol succinate. The failure to disclose was done with an intent to deceive the patent examiner as to this material dispute. AstraZeneca failed to provide material information in order to avoid questions concerning Astra's ability to claim priority to the '318 patent and to avoid potential prior art concerning metoprolol succinate.

62. Despite AstraZeneca's knowledge of the invalidity of its patents, Defendant launched a campaign of baseless litigation against KV Pharmaceuticals, Andrx and Eon, each of which had filed ANDAs seeking to manufacture and sell generic versions of Toprol-XL®. AstraZeneca knew that its litigation against its potential generic competitors amounted to little

more than a sham to unlawfully and artificially extend the life of its invalid patents. As a direct result of AstraZeneca's illegal monopoly, End-Payors like Plaintiff and the Class paid artificially inflated costs for extended release metoprolol succinate.

3. Monopoly Power

63. Through the anticompetitive conduct alleged herein, Defendant was able to charge supracompetitive prices for extended release metoprolol succinate, and thus, by definition, maintain monopoly power with respect to metoprolol succinate, sold in the United States.

64. Defendant's actions are part of, and in furtherance of, the illegal monopolization alleged herein, were authorized, ordered or done by Defendant's officers, agents, employers or representatives while actively engaged in the management of Defendant's affairs.

65. Defendant's illegal acts to prevent the introduction and/or dissemination into the U.S. marketplace of any generic version of Toprol-XL® resulted in Plaintiff and the Class paying more than they would have paid for extended release metoprolol succinate, absent Defendant's illegal conduct.

4. Effects on Competition and Damages to Plaintiff and Class

66. Defendant's exclusionary conduct has delayed or prevented the sale of generic extended release metoprolol succinate in the United States, and unlawfully enabled Defendant to sell Toprol-XL® at artificially inflated prices. But for Defendant's illegal conduct, generic competitors would have been able to successfully market generic versions of Toprol-XL® capsules by at least May 6, 2003, and additional generic competitors would have entered the market thereafter. Moreover, to the extent that demand for extended release metoprolol succinate tablets would have existed but for Defendant's illegal conduct, generic competitors would have begun marketing generic versions of Toprol-XL® at an earlier point in time.

67. Defendant's actions, designed to delay generic entry of extended release metoprolol succinate, are exclusionary and unreasonably restrained competition. To the extent that AstraZeneca had any valid business purpose for its conduct, that purpose could be served by means that are less restrictive of competition, and would, in any event, be outweighed by the anticompetitive effects of the conduct.

68. If manufacturers of generic extended release metoprolol succinate had been able to enter the marketplace and effectively compete with Defendant earlier, as set forth above, Plaintiff and other members of the Class would have substituted lower-priced generic extended release metoprolol succinate for the higher-priced brand-name Toprol-XL® for some or all of their extended release metoprolol succinate requirements, and/or would have received discounts on some or all of their remaining Toprol-XL® purchases.

CLASS ACTION ALLEGATIONS

69. Plaintiff brings this action on behalf of itself and as representatives of the following class as defined as follows:

All end-payors who are either located in the Indirect Purchaser States or who made purchases and/or paid for Toprol-XL® in the Indirect Purchaser States during the period May 6, 2003 to the present (the "Class Period") for consumption by themselves, their families, or their members, employees, insureds, participants or beneficiaries (the "Class"). For purposes of the Class definition, persons and entities "purchased" Toprol-XL® if they paid some or all of the purchase price.

70. Plaintiff seeks class certification pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure.

71. Numerosity: The members of the Class are so numerous that joinder of all members is impracticable. Toprol-XL® had annual sales in 2005 in excess of \$1.29 billion.

There were thousands, if not hundreds of thousands, of prescriptions written for the benefit of End-Payors (and/or their members, participants and beneficiaries).

72. **Commonality:** Common questions of law and fact exist as to all members of the

Class and predominate over any questions, if any, that may affect only individual members. This is particularly true given the nature of Defendant's conspiracy which was generally applicable to the entire Class, thereby making appropriate relief with respect to the Class as a whole. Such conduct includes Defendant's exclusionary and anti-competitive efforts: (i) in committing fraud on the United States Patent and Trade office; (ii) in filing sham litigation; and (iii) converting the relevant market from one confronted with generic competition to one that is not, for the sole purpose of monopolizing and attempting to monopolize the market for Toprol-XL®.

73. Common questions of law and fact include, but are not limited to:

- a. whether Defendant maintained or attempted to maintain monopoly power by delaying generic entry in the relevant market;
- b. whether Defendant intentionally and unlawfully excluded competitors and potential competitors from the market for Toprol-XL® and generic bioequivalents to Toprol-XL®;
- c. whether Defendant's litigation asserting infringement of the '161 and '154 patents was objectively baseless;
- d. whether Defendant made fraudulent representations to the PTO regarding its '161 and '154 patents; and
- e. whether Plaintiff and the Class have been damaged and the aggregate amount of damages.

74. **Typicality:** Plaintiff's claims are typical of the members of the Class, in that Plaintiff purchased and/or paid for Toprol-XL® throughout the United States, including the Indirect Purchaser States, during the Class Period. Such purchases and payments were made for consumer consumption of Toprol-XL®. Additionally, Plaintiff's claim is typical of the claim of the Class because AstraZeneca's conspiracy to perpetuate an illegal monopoly *vis-à-vis* its sham patent applied equally to each and every member of the Class. To that end, all Class members paid inflated costs for metoprolol succinate extended release tablets due directly to AstraZeneca's efforts to deter, delay and/or defeat generic entrants into the marketplace. As a direct and proximate result of AstraZeneca's conspiracy, Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendant.

75. **Adequacy:** Plaintiff will fairly and adequately protect and represent the interests of the Class. The interest of the Plaintiff is not antagonistic to those of the Class. Further, Plaintiff's attorneys are skilled in the prosecution of complex antitrust class action litigation.

76. **Predominance:** The central allegations in this case revolve around AstraZeneca's illegal monopolistic conspiracy. Accordingly, the quantum of evidence required to establish AstraZeneca's culpability does not vary from Class member to Class member. These issues predominate over all other issues and include, but are not limited to: 1) whether AstraZeneca committed a fraud on the patent office in the procurement of patent protection for its extended release metoprolol succinate drug; 2) whether AstraZeneca engaged in sham litigation to defend the '161 and '154 patent and 3) whether AstraZeneca's sham litigation resulted in the formation of an illegal monopoly.

77. **Superiority:** Class action treatment is a superior method for the fair and efficient adjudication of the controversy, in that, among other things, such treatment will permit a large

number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress for claims that it might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

78. **Manageability:** Manageability will not be an impediment to certifying this case as a class action. Adequate procedures will be available not only to identify the potential class members, but also to determine the amount of overcharge damages to which each member of the class is entitled.

FIRST CAUSE OF ACTION

COMPENSATORY AND MULTIPLE DAMAGES UNDER THE ANTITRUST AND/OR CONSUMER PROTECTION STATUTES OF THE INDIRECT PURCHASER STATES AND JURISDICTIONS AS OUTLINED BELOW

79. Plaintiff repeats and realleges the preceding paragraphs as if fully set forth below.

80. Defendant's conduct described herein constitutes unlawful acts under the antitrust and/or consumer protection laws of the Indirect Purchaser States, as follows:

<u>Alaska</u>	Alaska Stat. § 45.50.471, <i>et seq.</i>
<u>Arizona</u>	A.R.S. § 44-1402, <i>et seq.</i>
<u>Arkansas</u>	AR. Stat. Ann. § 4-75-201, <i>et seq.</i>
<u>California</u>	Cal. Bus. & Prof. Code §§ 16720, <i>et seq.</i> and 17200 <i>et seq.</i>
<u>District of Columbia</u>	D.C. Code § 28-4501, <i>et seq.</i>
	D.C. Code § 28-3901, <i>et seq.</i>

<u>Florida</u>	Florida Statutes § 501.204, <i>et seq.</i>
<u>Hawaii</u>	Haw. Rev. Stat. § 480-1, <i>et seq.</i>
<u>Illinois</u>	740 Ill. Comp. Stat. Ann. 10/1, <i>et seq.</i>
<u>Iowa</u>	IA. R. Stat. § 553.1, <i>et seq.</i>
<u>Kansas</u>	Kan. Stat. Ann. § 50-101, <i>et seq.</i>
	Kan. Stat. Ann. § 50-626(b)
<u>Louisiana</u>	La. Rev. Stat. § 51:1401, <i>et seq.</i>
<u>Maine</u>	10 M.R.S.A. § 1101, <i>et seq.</i>
	5 M.R.S.A. § 207
<u>Michigan</u>	M.C.L.A. § 445.772, <i>et seq.</i>
<u>Minnesota</u>	Minn. Stat. Ann. § 325D.49, <i>et seq.</i>
<u>Mississippi</u>	Miss. Code Ann. § 75-21-1, <i>et seq.</i>
<u>Montana</u>	Mont. Code Ann. § 30-14-201, <i>et seq.</i>
<u>Nebraska</u>	Neb. Rev. Stat. § 59-1609, <i>et seq.</i>
<u>Nevada</u>	Nev. Rev. Stat. § 598A.010, <i>et seq.</i>
<u>New Mexico</u>	N.M. Stat. Ann. § 57-1-3
	N.M. Stat. Ann. § 57-12-3
<u>New York</u>	N.Y. Gen. Bus. § 340, <i>et seq.</i>
	N.Y. Gen. Bus. § 349
<u>North Carolina</u>	N.C. Gen. Stat. § 75-1, <i>et seq.</i>
<u>North Dakota</u>	N.D. Cent. Code § 51-08.1-08
	N.D. Cent. Code § 51-15-02

<u>Puerto Rico</u>	10 LPRA § 257, <i>et seq.</i>
	32 LPRA § 5141
<u>South Dakota</u>	S.D. Codified Laws Ann. §§ 37-1-14.3, 37-1-33
<u>Tennessee</u>	Tenn. Code Ann. § 47-25-101,
	Tenn. Code Ann. § 47-25-106
<u>Utah</u>	Utah Code Ann. § 76-10-919
	Utah Code Ann. § 76-10-926
<u>Vermont</u>	Vt. Stat. Ann. Title 9, §§ 2451-2480g
<u>Virginia</u>	Va. Code Ann. § 59.1-9.1
<u>West Virginia</u>	W.Va. Code § 47-18-1, <i>et seq.</i>
	W. Va. Code § 46A-6-104 and § 47-11A-1, <i>et seq.</i>
<u>Wisconsin</u>	Wis. Stat. § 133.01, <i>et seq.</i>

81. As a direct and proximate result of Defendant's violations of the aforementioned statutes, Plaintiff and the Class have been injured in an amount to be proven at trial.

82. Pursuant to the antitrust statutes in those states, Plaintiff has provided notice of this Complaint to the attorneys general of Arizona, Nevada, and New York.

SECOND CAUSE OF ACTION

UNJUST ENRICHMENT

83. Plaintiff repeats and realleges the preceding paragraphs as if fully set forth below.

84. As a result of its unlawful conduct described above, Defendant has and will continue to be unjustly enriched. Defendant has been unjustly enriched by the receipt of, at a minimum, unlawfully inflated prices and illegal profits on the sale of Toprol-XL®.

85. Defendant has benefited from its unlawful acts and it would be inequitable for Defendant to be permitted to retain any of the ill-gotten gains resulting from the overpayments made by class members for its Toprol-XL® product.

86. Plaintiff and members of the Class are entitled to the amount of Defendant's ill-gotten gains resulting from its unlawful, unjust and inequitable conduct. Plaintiff and the Class are entitled to the establishment of a constructive trust consisting of all ill-gotten gains from which Plaintiff and the Class members may make claims on a *pro rata* basis.

JURY TRIAL DEMAND

Pursuant to Fed. R. Civ. P. 38(b), Plaintiff demands a trial by jury of all of the claims asserted in this Complaint so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that:

(a) the Court determine that this action may be maintained as a class action pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure with respect to the claims for damages, and declaring Plaintiffs as representatives of the Class and their counsel as counsel for the Class; and

(b) the conduct alleged herein be declared, adjudged and decreed to be unlawful monopolization and attempt to monopolize in violation of the statutes of the Indirect Purchaser States set forth above, and the common law of unjust enrichment; and

(c) Plaintiff and each member of the Class recover the amounts by which the Defendant has been unjustly enriched; and

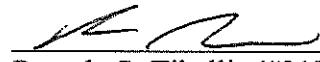
(d) Defendant be enjoined from continuing the illegal activities alleged herein; and

(e) Plaintiff and the Class recover their costs of suit, including reasonable attorneys' fees and expenses as provided by law; and

(f) Plaintiff and the Class be granted such other, further, and different relief as the nature of the case may require or as may be determined to be just, equitable, and proper by this Court.

Date: February 15, 2006

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Attorneys for Plaintiff and the Class

CIVIL COVER SHEET

JS 44 (Rev. 11/04)

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS PLUMBERS AND PIPEFITTERS LOCAL 572 PENSION FUND, on behalf of itself and all others similarly situated (b) County of Residence of First Listed Plaintiff <u>Davidson County</u> <small>(EXCEPT IN U.S. PLAINTIFF CASES)</small>		DEFENDANTS ASTRAZENECA PHARMACEUTICALS LP a Delaware Corporation, ASTRAZENECA LP, ASTRAZENECA AB, AKTIEBOLAGET HASSELE County of Residence of First Listed Defendant _____ <small>(IN U.S. PLAINTIFF CASES ONLY)</small> NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.	
(c) Attorney's (Firm Name, Address, and Telephone Number) (302) 656-2500 <u>Chimicles & Tikellis LLP, One Rodney Square, Wilmington, Delaware 19801</u>		Attorneys (If Known)	
II. BASIS OF JURISDICTION (Place an "X" in One Box Only)		III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant) <small>(For Diversity Cases Only)</small>	
<input type="checkbox"/> 1 U.S. Government Plaintiff		<input checked="" type="checkbox"/> 1 Federal Question (U.S. Government Not a Party)	
<input type="checkbox"/> 2 U.S. Government Defendant		<input checked="" type="checkbox"/> 4 Diversity <small>(Indicate Citizenship of Parties in Item III)</small>	
		Citizen of This State <input type="checkbox"/> 1 <input checked="" type="checkbox"/> 1 Incorporated or Principal Place of Business In This State <input type="checkbox"/> 4 <input checked="" type="checkbox"/> 4	PTF DEF
		Citizen of Another State <input type="checkbox"/> 2 <input checked="" type="checkbox"/> 2 Incorporated and Principal Place of Business In Another State <input type="checkbox"/> 5 <input checked="" type="checkbox"/> 5	PTF DEF
		Citizen or Subject of a Foreign Country <input type="checkbox"/> 3 <input checked="" type="checkbox"/> 3 Foreign Nation <input type="checkbox"/> 6 <input checked="" type="checkbox"/> 6	PTF DEF

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excl. Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury	PERSONAL INJURY <input type="checkbox"/> 362 Personal Injury - Med. Malpractice <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability	<input type="checkbox"/> 610 Agriculture <input type="checkbox"/> 620 Other Food & Drug <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 630 Liquor Laws <input type="checkbox"/> 640 R.R. & Truck <input type="checkbox"/> 650 Airline Regs. <input type="checkbox"/> 660 Occupational Safety/Health <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	SOCIAL SECURITY	400 State Reapportionment <input checked="" type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 810 Selective Service <input type="checkbox"/> 850 Securities/Commodities Exchange <input type="checkbox"/> 875 Customer Challenge 12 USC 3410 <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 892 Economic Stabilization Act <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 894 Energy Allocation Act <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 900 Appeal of Fee Determination Under Equal Access to Justice <input type="checkbox"/> 950 Constitutionality of State Statutes
			LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Mgmt. Relations <input type="checkbox"/> 730 Labor/Mgmt. Reporting & Disclosure Act <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

V. ORIGIN (Place an "X" in One Box Only)						
<input checked="" type="checkbox"/> 1 Original Proceeding <input type="checkbox"/> 2 Removed from State Court <input type="checkbox"/> 3 Remanded from Appellate Court <input type="checkbox"/> 4 Reinstated or Reopened <input type="checkbox"/> 5 Transferred from another district (specify) _____ <input type="checkbox"/> 6 Multidistrict Litigation <input type="checkbox"/> 7 Appeal to District Judge from Magistrate Judgment						

VI. CAUSE OF ACTION _____ <small>Brief description of cause:</small> Civil antitrust action in connection with the monopolization of market for Toprol XL						
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VII. REQUESTED IN COMPLAINT: <input checked="" type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23		DEMAND \$	CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		
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VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE GMS/UNA		06-52, 06-63, 06-73 DOCKET NUMBER 06-93, 06-79, 06-81		
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DATE	SIGNATURE OF ATTORNEY OF RECORD		
<u>2-15-06</u>	<u>Robert R. Davis (#4536)</u>		
FOR OFFICE USE ONLY			

RECEIPT # _____ AMOUNT _____ APPLYING IFFP _____ JUDGE _____ MAG. JUDGE _____

AO FORM 85 RECEIPT (REV. 9/04)

United States District Court for the District of Delaware

Civil Action No.

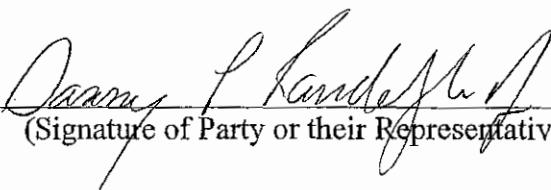
06 102-

ACKNOWLEDGMENT
OF RECEIPT FOR AO FORM 85

NOTICE OF AVAILABILITY OF A
UNITED STATES MAGISTRATE JUDGE
TO EXERCISE JURISDICTION

I HEREBY ACKNOWLEDGE RECEIPT OF 3 COPIES OF AO FORM 85.

FEB 15 2006
(Date forms issued)


(Signature of Party or their Representative)

DANNY P. RANDOLPH JR.
(Printed name of Party or their Representative)

Note: Completed receipt will be filed in the Civil Action